



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/014,935

12/11/2001

Ursula Mariah Rothlin

22094

1036

535

7590

10/06/2003

THE FIRM OF KARL F ROSS

5676 RIVERDALE AVENUE

PO BOX 900

RIVERDALE (BRONX), NY 10471-0900

EXAMINER

COE, SUSAN D

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 10/06/2003

48

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/014,935

Applicant(s)

ROTHLIN, URSULA MARIAH

Examiner

Susan Coe

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-35 is/are pending in the application.
- 4a) Of the above claim(s) 14-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1654

DETAILED ACTION

1. The amendment filed July 17, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 35 has been added.
3. Claims 14-35 are pending.

Election/Restrictions

4. Applicant's election with traverse of Group II, claims 33, 34, and new claim 35 and the species of claim 35 in Paper No. 7, dated July 17, 2003 is acknowledged. The traversal is on the ground(s) that the composition could not be used for any purpose other than as an aid in smoking cessation. The applicant argues that the composition could not be used in amino acid replacement therapy because the amount of amino acids in the composition is too small to be used for this purpose. This is not persuasive because the composition does contain amino acids. Therefore, it can be used to replace amino acids for a patient in need thereof. This use shows that the composition can be used for a different purpose. This is sufficient grounds for restriction.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 14-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.
6. Claims 33-35 are examined on the merits.

Art Unit: 1654

7. A search of the elected species indicates that claim 35 is free of the art. However, the allowability of this claim cannot be definitely determined because it is unclear what “escolsica californica” is. A search of this term did not produce any results and the specification does not provide any description that would allow a person of ordinary skill in the art to determine what this ingredient is. However, in the interest of compact prosecution, claim 35 appears free of the art. Accordingly, another species was selected by the examiner for examination. The examiner selected tyrosine for the amino acid and melissa officinalis for the plant extract.

Claim Objections

8. Claims 33 and 34 are objected to because they depend from non-elected claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is indefinite because it is unclear what “escolsica californica” is. A search of this term did not produce any results and the specification does not provide any description that would allow a person of ordinary skill in the art to determine what this ingredient is.

Art Unit: 1654

Claim Rejections - 35 USC § 103

10. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,132,724.

As stated above, claims 33 and 34 are examined in regards to the species of tyrosine for the amino acid and melissa officinalis for the plant. The common name for melissa officinalis is chamomile.

US '724 teaches a method of smoking cessation using a composition that comprises tyrosine and chamomile (see column 65, table 5 and columns 68 and 69, Table 10, "Nicarest"). The reference does not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

In addition, the reference does not specifically teach adding sorbitol to the composition. However, it is well known in the art that sorbitol is a common ingredient to add to pharmaceutical compositions. Therefore, it is considered an obvious modification of the composition taught by the reference to add sorbitol.

Art Unit: 1654

11. No claims are allowed. However, as stated above, claim 35 appears to be free of the art except for the lack of a definition for "escolsica californica."

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner
October 2, 2003



LEON B. LANKFORD, JR.
PRIMARY EXAMINER